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09/385,405	08/30/1999	WILLIAM J. SCHMIDT	671.1.002CIP	9104

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EXAMINER

POPOVICS, ROBERT J

ART UNIT

PAPER NUMBER

1724

DATE MAILED: 08/13/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-35

# Office Action Summary

Application No.

09/385,405

Applicant(s)

SCHMIDT, WILLIAM J.

Examiner

Robert J. Popovics

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 5/20/03.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 71-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                      6) ☐ Other: \_\_\_\_\_.

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DETAILED ACTION

*Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 71-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 71 now recites ***“said waste material containing at least one first component which can not effectively be separated from the first liquid into a non-solvent based layer.”*** This recitation is unsupported by the originally filed specification. Newly submitted claim 72 goes on to claim ***“The method of claim 1 wherein the first component is selected from oily type materials, particulates and combinations thereof having an affinity for the solvent.”*** The specification does not say anything about any materials having ***“an affinity for the solvent.”*** These recitations constitute new matter.

3. Claim 72 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's originally filed specification fails to teach those skilled in the art how to differentiate between those ***“particulate and/or oily type”*** contaminants of a trace nature from those having an affinity for the solvent based layer, and **now** asserted to be the subject of invention.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 71-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 71, it is unclear what Applicant intends by the recitation ***“said waste material containing at least one first component which can not effectively be separated from the first liquid into a non-solvent based layer.”*** It is unclear what Applicant intends by ***“effectively,”*** in the context used. Is this intended to refer to residual or trace amounts? It is unclear why this ***“first component”*** cannot be effectively separated.

Applicant has argued (Response - Paper no. 26):

Reference is first made to page 13, lines 11-13 wherein it is stated that the separated solvent based layer (e.g., aqueous layer) contains particulates and/or oily type materials (the contaminants of interest in the present invention). (Response pg. 7, lines 8-10)

As will become more fully apparent from the discussion below, the present invention is principally concerned with removing those contaminants which reside in the solvent based layer and not in the non-solvent based layer which is the subject of the reference cited herein (U.S. Patent No. 5,288,408). (Response pg. 7, lines 17-21)

These arguments have raised new issues requiring clarification. With respect to the first sentence, Applicant has positively asserted that ***“the solvent based layer (e.g., aqueous layer) contains particulates and/or oily type materials (the contaminants of interest in the present invention).”*** In other words, Applicant has asserted that at least one of these components is necessarily present. This is inconsistent with the specific portion of the specification referenced by Applicant. The referenced sentence (i.e., page 13, lines 11-13) begins with the word ***“If.”***

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Specifically, the sentence appearing at page 13, lines 11-13 reads: **“If the separated aqueous layer contains particulates and/or oily type materials, the aqueous layer may then be treated, to remove residual oils and/or particulates by means of hot filtration processes as more fully described below.”** Given that there may not be any of the *“the contaminants of interest in the present invention”* **present**, as Applicant’s specification makes clear, the meaning of claim 71 and those claims dependent thereon, is unclear, when those contaminants are not present. Moreover, it is unclear how one skilled in the art would differentiate between the two different types (i.e., those having an affinity for the solvent based layer, and those not having said affinity) of contaminants argued to be present in Applicant’s most recent response, since Applicant’s **originally filed** specification makes no such distinctions. In other words, it is unclear how potential infringers would be put on notice.

6. Claims 71-83 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 71-83 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Applicant’s specification at page 4, lines 1-16, and page 5, lines 3-8. There, Applicant has stated (when discussing the Schmidt et al. Patent - U.S. Patent No. 5,288,408) **“A pure, concentrated aqueous gelatin-glycerin solution results which may be stored or further prepared for immediate reuse. Although this process lends itself to the removal of dyes and active ingredients with additional chemical reactions and processing, such dyes, active ingredients, and glycerin are not removed *in situ*,”** and this statement indicates that the invention is different from what is defined in the claim(s) because the claims fail to mention

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anything about being "*in situ*." One skilled in the art reading the cited portions of the specification would clearly agree that Applicant had admitted that recycling gelatin-based encapsulation waste material using the method disclosed in the '408 patent resulted in "*A pure, concentrated aqueous gelatin-glycerin solution*," but that Applicant's instant invention somehow involved "*in situ*" processing.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 71-73, 75-81 and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt (US 5,288,408).

9. In the '408 patent to Schmidt, one of the objects is stated to be:

Still another object of the present invention is to provide a recycled gelatin product with chemical and physical properties identical to virgin gelatin such that reuse may be successfully accomplished.

10. At column 3, the following is disclosed:

The soft elastic capsule-forming material will thus be used to enclose active ingredients in the form of powders, liquids or combinations thereof. Oils, such as vitamin A, vitamin E and beta-carotene, for example, are frequently encapsulated in the pharmaceutical industry. Additionally, other oils like mineral oil may be used to coat the outer surface of the gel-capsule during processing. Thus, it can be seen that the encapsulation waste product may have many components to be removed for reuse. In some instances, coloring agents and preservatives may also be incorporated into the encapsulation melt. Commonly used preservatives are methyl- and propylparabens and sorbic acid.

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As stated above, present methods of encapsulation lose as much as 50% of the melt during processing, the balance of which is either discarded as a waste by-product or recycled. The latter option requires the removal of all of the above components with the exception of gelatin and glycerine. The present invention provides a novel and efficient method of accomplishing same without experiencing the shortcomings of the prior art.

11. At column 4, lines 22-31, it is disclosed that:

Next, the lower phase is hot filtered to remove any remaining traces of oil or other contaminants. Stainless steel filtration equipment may be employed such as a plate filter, or a coated plate filter like, for example, a Sparkler filter. Alternatively, nutche filters of the Rosenmund type or cartridge filters may be used for the purpose. Here again, the residue may be recaptured for further separation and purification if desired although the amounts involved at this point may not warrant the effort.

12. Claim 6 teaches:

6. The process for recovering and purifying waste gelatin and glycerine of claim 1, wherein the step of hot filtering said aqueous gelatin/glycerine solution is accomplished by use of one of the following filters: (a) a plate filter; (b) a coated plate filter; (c) a nutche filter; or (d) a cartridge filter.

13. Claim 20 teaches:

20. The apparatus of claim 12 wherein said means for hot filtration is a cartridge filter.

14. In order to remove *“all of the above components,”* including *“traces”* of *“coloring agents,”* *“oils and other contaminants,”* from the lower aqueous phase (i.e., “solvent based phase”) to attain a *“recycled gelatin product with chemical and physical properties identical to virgin gelatin,”* any *“cartridge filter”* used would necessarily have the ability, regardless of the filtration process label placed upon it, to accomplish this task. That is to say that any *“cartridge filter”* used would have inherently possessed the ability to accomplish the stated objective. The

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'408 patent is clear, that a *"cartridge filter"* may be used *"to remove any remaining traces of oil or other contaminants"* from the aqueous/lower phase!

With respect to claim 72, the '408 process will inherently remove all particulate and oily type contaminants. With respect to claim 76, it is submitted that the specified range of "up to 5 volumes" corresponds to a solution having a "preferred concentration of 10% to 12% gelatin/glycerine by weight," since this is disclosed by Schmidt et al. as "the optimum concentration for achieving rapid and thorough separation of the two layers" at column 3, lines 60-65.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 71-73, 75-81 & 83 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (U.S. Patent No. 5,288,408).

Schmidt et al. disclose a method of gelatin recovery. As illustrated in Fig. 1, waste material is dissolved with a solvent in an agitated tank and separated into an aqueous/lower phase stream and an upper/organic phase stream. The resultant aqueous phase stream is then subjected to heat and hot filtered, *"to remove any remaining traces of oil or other contaminants."* A resultant gelatin/glycerine filtrate is then heated and subjected to vacuum distillation in order to



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concentrate (i.e., dewater) the resultant, purified filtrate. The recovered gelatin and glycerine may then be immediately re-used (col. 2, lines 33-35 & col. 5, lines 5-10). Beyond disclosing the use of a "cartridge filter" as one possible type of filter to be used, the '408 patent does not go into the details of the pore size, material of construction, etc., of a "cartridge filter" which would be suitable for the stated purpose. Obviously, no such details were provided, since Schmidt et al. knew that the selection of a such filter would have been well within the purview of the skilled artisan. Indeed, numerous filters existed prior to issuance of the '408 patent which could have handled the separation of "trace" amounts of oil, or "other contaminants" from a liquid stream.

Claim 76 specifies a dilution volume "of up to 5 volumes of said solvent." Schmidt et al. do not express the dilution in terms of volumes, but rather, they disclose "the optimum concentration for achieving rapid and thorough separation of the two layers" at column 3, lines 60-65.. It is submitted that one of ordinary skill in the art obviously would have been able to handle the conversion, in order to express the optimum concentration in terms of dilution volumes, in order to obtain optimum separation.

17. Claims 74 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of **Schmidt et al.** (U.S. Patent No. 5,288,408) and **Dutre et al.** (Purification of Gelatin by Ultrafiltration with a Forced Solvent Stream along the Membrane Permeate Side: An Experimental Approach - Journal of Food Engineering © 1995).

Schmidt et al. do not expressly disclose the use of tangential flow filtration as recited in claim 74, or ultrafiltration as recited in claim 82. Dutre et al. disclose the use of tangential flow tubular membrane ultrafiltration to concentrate Gelatin (see Fig 1(b)). Page 234 of Dutre et al.

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discloses the benefits associated with ultrafiltration concentration of the gelatin solution, namely, lower costs and higher purity. Accordingly, it would have been obvious to concentrate the gelatin solution of Schmidt et al., using an ultrafilter in order to obtain a concentrated gelatin solution.

***Response to Arguments***

18. Applicant's arguments filed May 20, 2003 have been fully considered but they are not persuasive. Applicant has argued:

**At the outset, it should be noted that Applicant has filed a Notice of Appeal and Appeal Brief in response to the final Office Action of May 21, 2002. It was Applicant's position then, as it is now, to take this matter before the Board of Appeals in view of the untenable position taken by the Examiner not only with the respect to the claimed technology but the characterization of the Schmidt et al. prior art.**

If it was Applicant's intent to take this matter to the Board, then it is unclear why Applicant did not request reinstatement of the appeal, an option that the last Office Action clearly set forth. Applicant's remarks to this end, puzzle the Examiner, since Applicant's remarks imply that the Examiner somehow precluded Applicant from taking this matter before the Board.

Regarding the double patenting rejection, Applicant has correctly pointed out, that the language constituting new matter in claim 71 precludes a double patenting rejection, since the '802 patent does not teach a ***"first component which cannot be effectively separated from the initial liquid formed when a solvent is added to the waste gelatin material,"*** as argued by Applicant. For this reason, the double patenting rejection is withdrawn.

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***Conclusion***

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Robert Popovics whose telephone number is (703) 308-0684.

A handwritten signature in black ink, appearing to read 'R. Popovics', with a large, stylized initial 'R' and a long, sweeping horizontal line extending to the right.

**Robert James Popovics**  
**Primary Examiner**  
**Art Unit 1724**

ryp  
August 9, 2003